

Amendments to the Specification

Please add the following paragraphs after the paragraph that ends on page 6, line 2:

The present invention also relates to a method of inducing a protective immune response, the method comprising orally administering to a subject therapeutically effective amounts of at least a first and second subpopulation of microparticles, wherein each of the microparticles comprises an antigen entrapped or encapsulated by a biocompatible, biodegradable polymer, and wherein the antigen in the microparticles of the first subpopulation is different than the antigen in the microparticles of the second subpopulation and at least 50% of the microparticles are less than 5 μm .

The present invention further relates to a method of inducing a protective immune response, the method comprising orally administering to a subject therapeutically effective amounts of at least a first and second subpopulation of nanoparticles, wherein each of the nanoparticles comprises an antigen entrapped or encapsulated by a biocompatible, biodegradable polymer, and wherein the antigen in the nanoparticles of the first subpopulation is different than the antigen in the nanoparticles of the second subpopulation and at least 50% of the microparticles are less than 600 nm.

Please delete the paragraph on page 7, lines 21 to 28.

Please amend the paragraph on page 24, lines 1 to 17, to recite:

Mice were challenged 2 weeks after the third immunisation. A rapid initial drop in CFU counts was observed in mice immunised with FHA and PTd entrapped in PLGA nanoparticles (~~Figure 7~~). At 3 days, the CFU counts were 1.5 logs lower than in the mice immunised with the antigens in solution and more than 3 logs lower than the controls. A typical rebound in the CFU counts is observed at day 7. The overall protection with the PLGA entrapped pertussis antigens appears to be significantly better than with the antigens in solution. Assigning a potency index to the protection according to the formula describe in Mills, et al. *Dev. Biol. Std.* 95:21-41 (1998), values of 62.8 and 44.8 can be assigned to the PLGA entrapped and soluble antigens, respectively. Extrapolation from the correlation curve translates to 73% and 48% efficacy in children. They reveal a high level of protection in animals orally immunised with a blend of nanoparticles entrapping PTd and FHA respectively. While soluble antigens were also protective, the clearance was less effective than the PLG formulation at each timepoint. The efficacy of the nanoparticle entrapped in FHA and PTd is roughly comparable with that observed for the solvent evaporated microparticles delivered by the oral route according to Example 7 (67% efficacy in children).